REMARKS

The Official Action dated December 26, 2006 has been carefully considered. It is believed that the present Amendment places this application in condition for allowance. Reconsideration is respectfully requested.

By the present Amendment, claim 2 is amended to recite the phrase "binding capability" in accordance with the teachings of the specification at page 15, lines 4-8. claim 5 is amended to correct a typographical error and to omit recitation of conditions in the flow matrix, and claims 11 and 17 are amended to clarify reference to one or more library members of a chemical library, in accordance with the teachings in the specification at page 4, lines 27-29 and page 15, lines 4-11. Claim 1 has also been amended to omit the optional component, while new claims 18-21 are directed to a method as previously set forth in claim 1, including the analytically detectable reactant as a required component. Claims 19-21 additionally contain limitations from claims 3, 9 and 10, respectively. It is believed that these changes do not involve any introduction of new matter, whereby entry is believed to be in order and is respectfully requested.

In the Official Action, claims 2-17 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner asserted that the flow matrix having a separation zone containing a ligand for which the "binding capacity" for the analyte is to be determined is not supported by the specification. This rejection is traversed and reconsideration is respectfully requested. Specifically, the phrase "binding capacity" as previously recited in claim 2 has been omitted and claim 2 now recites a separation zone containing a ligand for which the "binding capability" for the analyte is to be determined, in accordance with the teachings of the specification at page 15, lines 1-4. It is therefore submitted that claim 2, and claims 3-17 dependent thereon, are described in the present specification in accordance with the written description requirements

of 35 U.S.C. §112, first paragraph, whereby this rejection has been overcome. Reconsideration is respectfully requested.

Claims 2-17 were also rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Examiner asserted that claim 2 was vague and indefinite owing to recitation of "binding capability" in the preamble and "binding capacity" in the separation zone, and the Examiner asserted that the "optional limitation" was indefinite and was not given patentable weight. The Examiner asserted that claim 5 was vague because it is unclear exactly what conditions make the ligand exhibit positive and negative charges at the same time and that claims 11 and 17 were confusing in reciting "library members of a library of compounds."

This rejection is traversed and reconsideration is respectfully requested. As noted above, the phrase "binding capacity" has been omitted from claim 2. Additionally, the reference to conditions has been omitted from claim 5. Accordingly, claim 5 recites that the ligand exhibits one or more positive and/or negative charges in the flow matrix. Compounds carrying both a positive and negative charge are well known as zwitterions (see, for example, the *American Heritage® Dictionary of the English Language, 4th Edition*, at dictionary.com website: http://dictionary.reference.com/browse/zwitterion. Finally, claims 11 and 17 recite that the ligand comprises one or more library members of a chemical library. Chemical libraries are well known in the art as demonstrated, for example, by the Cook U.S. Patent No. 5,780,241 entitled "Complex Chemical Libraries." Accordingly, claims 2-17 presented herein are definite to one of ordinary skill in the art in accordance with the requirements of 35 U.S.C. §112, second paragraph, whereby the rejection has been overcome. Reconsideration is respectfully requested.

Finally, claims 2-17 were rejected under 35 U.S.C. §102(b) as being anticipated by the Fitzpatrick et al U.S. Patent No. 5,451,504. The Examiner asserted that Fitzpatrick et al disclose a device comprising an application zone, an immobilization zone, a trap zone, a

detection zone, and an absorbent zone, wherein the trap zone comprises immobilized ligand that will bind either free receptor or excess analyte and the detection zone comprises immobilized capture reagent for the analyte-labeled receptor complex. In response to Applicants' previous arguments, the Examiner asserted that Fitzpatrick et al clearly teach a detection zone comprising an immobilized binding partner of the receptor which binds receptor bound to analyte and therefore meets the limitation of the biospecific affinity capturer directed toward an analyte-related reactant.

This rejection is traversed and reconsideration is respectfully requested. More particularly, as defined by claim 2, the present invention is directed to a test kit for determining the binding capability of ligand to an analyte. The kit comprises a flow matrix comprising an application zone for analyte, a detection zone and a separation zone. A biospecific affinity capture reactant directed toward the analyte or toward analyte-related reactant is firmly anchored in the detection zone, and a separation zone is arranged between the application zone for analyte and the detection zone. The separation zone contains a ligand for which the binding capacity for the analyte is to be determined. As described in the present specification, for example at page 15, lines 4-11, the test kits according to the invention are particularly suitable for determining the binding capability of an analyte for the ligand contained in the separation zone. In a specific example, the test kit may be advantageous for screening of a chemical library, with one or more of the library members arranged as ligands in the separation zone.

Anticipation under 35 U.S.C. §102 requires that each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference, *In re Robertson*, 49 U.S.P.Q. 2d 1949, 1950 (Fed. Cir. 1999). Fitzpatrick et al do not describe each and every element of claim 1. That is, Fitzpatrick et al disclose an assay device for detecting the presence of an analyte in a sample wherein sample is applied to move through

three zones, a mobilization zone, a trap zone and a detection zone. In a first embodiment, receptor specific for the analyte of interest is provided in the mobilization zone (column 4, lines 51-53) and immobilized ligand that will bind free receptor moving through the trap zone but will not bind receptor bound in a receptor-analyte complex is provided in the trap zone (column 6, lines 38-41). Thus, in this embodiment, Fitzpatrick et al do not disclose a separation zone as required in claim 2 containing a ligand for which the binding capability for the analyte is to be determined, but rather a ligand for unbound receptor with known binding capability. Thus, notwithstanding the fact that the detection zone may contain an immobilized binding partner of the receptor bound to analyte, this embodiment of the Fitzpatrick et al device does not disclose each and every element as set forth in claim 2, or claims 3-17 dependent thereon.

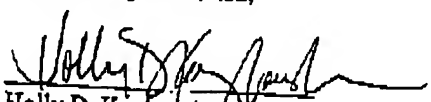
Fitzpatrick et al disclose an alternate embodiment wherein the mobilization zone may contain mobilizable ligand and the trap zone contains immobilized receptor (column 6, lines 42-44). In this embodiment, wherein ligand is mobilized upon introduction of the sample, the sample analyte binds with the known receptor in the trap zone and free ligand migrates to the detection zone which contains an immobilized capturer for the ligand. Thus, this second embodiment of Fitzpatrick et al fails to include a separation zone containing a ligand for which the binding capability for the analyte is to be determined, since the receptor is known to have a binding capability for the analyte. This embodiment of Fitzpatrick et al also fails to include a detection zone in which a biospecific affinity capture reactant directed towards the analyte or toward an analyte related reactant is firmly anchored, since the detection zone contains a capturer directed toward the ligand. Thus, the second embodiment of Fitzpatrick et al similarly fails to describe each and every element of claim 2, and claims 3-17 dependent thereon.

Further, contrary to the Examiner's assertion, Fitzpatrick et al do not disclose a trap zone that will bind excess analyte. Rather, in the first embodiment of Fitzpatrick discussed above, the trap zone binds free receptor (with immobilized ligand for free receptor) and in the second embodiment of Fitzpatrick discussed above, the trap zone binds ligand (on receptor which has not bound analyte). Each of these embodiments fails to employ both a separation zone and a detection zone as required by claim 2. Thus, Fitzpatrick et al fail to anticipate claim 2, or claims 3-17 dependent thereon, under 35 U.S.C. §102. Thus, Fitzpatrick et al do not anticipate these claims under 35 U.S.C. §102.

Accordingly, the test kits defined by claims 2-17 are not anticipated by and are patentably distinguishable from Fitzpatrick et al, whereby the rejections under 35 U.S.C. §102 have been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the rejections under 35 U.S.C. §§102 and 112, first and second paragraphs, and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,



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